**CONTRACT FOR OBSERVATIONAL TRIAL**

**Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Trial \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Classification: \_\_\_\_\_**

**Trial code**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Foundation code: CV21/XX / CEIm21/XX.**

Getafe, on [DATE]

# PARTIES

Mr./Ms. [FULL NAME], with National ID No. [ID NUMBER], acting on behalf of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, with Tax ID no. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and domicile in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, who is authorised by a power of attorney granted in [LOCATION] on [DATE], before the notary [FULL NAME OF NOTARY] with number [INSTRUMENT NUMBER], acting on behalf of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, with Tax ID No. G-28291235, acting on behalf of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, with Tax ID \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (hereinafter, **SPONSOR**) by virtue of commitments signed on [DATE].

**Mr. MIGUEL ÁNGEL ANDRÉS MOLINERO**, with National ID no. 13074648E, on behalf of **FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO DE GETAFE** (hereinafter, the **FOUNDATION**), with registered offices at Ctra. de Toledo, Km. 12,500, 28905 Getafe, Madrid and Tax ID no. G83727024, in his capacity as President of Patronato of the FOUNDATION.

**Mr. MIGUEL ÁNGEL ANDRÉS MOLINERO**, for and on behalf of the **SERVICIO MADRILEÑO DE SALUD** (hereinafter **SERMAS**), by virtue of Resolución 385/2020, de 11 de junio, de la Viceconsejera de Asistencia Sanitaria, de Delegación de Competencias en materia de contratación y gestión económico-presupuestaria, published in the BOCAM, dated June 15, 2020.

**Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**, with National ID no. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and professional address at the \_\_\_\_\_\_\_\_\_\_ Department, Hospital Universitario de Getafe, Ctra. de Toledo, Km. 12,500, 28905 Getafe, Madrid, Tax ID no. Q-2877037H, in his/her capacity as Principal Investigator (hereinafter **INVESTIGATOR**) and representing the investigation team for the trial with Trial Code no. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

The parties mutually acknowledge that they have the necessary legal capacity to bind themselves by means of this Contract.

#### WHEREAS

#### 1.- In accordance with the provisions of the current *Convenio General de Colaboración*, dated April 19, 2020, between the MADRID REGIONAL GOVERNMENT, through the CONSEJERÍA DE SANIDAD and SERMAS, and the FOUNDATION, the FOUNDATION's functions include entering into agreements for clinical trials conducted at the HOSPITAL and monitoring such trials.

**2**.- In accordance with the aforementioned Agreement, it is the responsibility of the **SPONSOR** of the trial and of the Director of the **FOUNDATION** o the person in whom he/she delegates, to sign the contract setting out the economic aspects related to the observational trials conducted at Hospìtal Universitario de Getafe, which is attached to Servicio Madrileño de Salud.

**3**.- By virtue thereof, the **SPONSOR** expresses interest in entering into an agreement with the **FOUNDATION** to conduct the observational trial entitled: “*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”* (hereinafter, the TRIAL) under the management of Researchers in the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Department at Hospital Universitario de Getafe, which has the necessary capabilities to undertake the Trial.

**4**.- The clinical and healthcare portion of the Trial will be performed in the facilities of Hospital Universitario de Getafe**,** in accordance with the protocol filed with the Oficina Técnica-Secretaría of the *Comité de Ética de la Investigación con Medicamentos* (Drug Research Ethics Committee — hereinafter **CEIm**) and with the legislation in force regarding observational post-authorisation trials studies linked to an authorisation to commercialise, subject to the ethical rules that govern them, including, but not limited to: *Real Decreto 957/2020, de 3 de noviembre, por el que se regulan los estudios observacionales con medicamentos de uso humano*, *Real Decreto Legislativo 01/2015, de 24 de julio, por el que se aprueba el Texto Refundido de la Ley de garantías y uso racional de los medicamentos y productos sanitarios*; the parts of *Ley 29/2006, de 26 de Julio, de garantías y uso racional de los medicamentos y de productos sanitarios* not abolished by the aforementioned Law); *Real Decreto 577/2013, de 26 de Julio, por el que se regula la farmacovigilancia de medicamentos de uso humano*; *Real Decreto 1345/2007, de 11 de octubre, por el que se regula el procedimiento de autorización, registro y condiciones de dispensación de los medicamentos de uso humano fabricados industrialmente*; *Orden SAS/3470/2009, de 16 de diciembre, por la que se publican las directrices sobre estudios posautorización de tipo observacional para medicamentos de uso humano*; *Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica*; Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), and any other domestic legislation that is enacted on the subject of data protection. *Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales*. *Ley 53/1984, de 26 de diciembre, de Incompatibilidades del Personal al Servicio de las Administraciones Públicas* and *Real Decreto 598/1985, de 30 de abril, sobre incompatibilidades del personal al servicio de la Administración del Estado, de la Seguridad Social y de los Entes, Organismos y Empresas dependientes*. In accordance with article 23 of *Ley 1/998, de 2 de marzo, de Fundaciones de la Comunidad de Madrid*, trustees may enter into agreements with the Foundation on their own behalf or on behalf of a third party subject to obtaining prior authorisation from *Protectorado de Fundaciones*.

**5**.- **SPONSOR** obtained clearance from the *Comité de Ensayos Clínicos con Medicamentos* of the [NAME OF HOSPITAL] on [DATE] and obtained clearance from the Management of Hospital Universitario de Getafe, attached to **SERMAS**, on [DATE].

# CLAUSES

ONE.- **Object of the contract**

**1.1**.- **SPONSOR** hereby engages the **FOUNDATION** to conduct the aforementioned trial, to be conducted basically in the facilities of Hospital Universitario de Getafe under the management of the **INVESTIGATOR** in accordance with the terms and conditions set out in the protocol.

**1.2.**- Duration

The research is expected to take **XX months** from the time the necessary authorisations are obtained and this contract is signed.

**1.3**.- The Trial will take place in strict compliance with its protocol and, in the event that **SPONSOR** amends this protocol, the latter undertakes to give notice of them and, if necessary, submit them for prior approval/vetting by the Hospital's *Comité de Ética de la Investigación con Medicamentos* (Drug Research Ethics Committee — **CEIm**).

**1.4**.- The Parties have the following obligations:

To cooperate with TRIAL monitoring visits performed by: (i) the **CEIm**, (2) monitors and auditors acting on instructions from **SPONSOR**, and (3) the competent authorities, when they perform inspections. At least one week's advance notice will be given of such visits except where a different time frame has been agreed by the Parties. During follow-up, monitoring and audit visits, such technical or organisational measures will be taken as are required to ensure the utmost compliance with the legislation on personal data protection.

The **INVESTIGATOR**, the **SPONSOR** and the monitors and auditors must conform to the internal procedural rules of the **HOSPITAL** and the **FOUNDATION**, and also to the instructions on the performance of the TRIAL given by the CEIm responsible for monitoring it.

In any event, the Monitors will act in strict compliance with the Protocol and will only have access to the documentation and clinical history of the patients who are enrolled, provided that the Principal Investigator or a member of the research team is present to ensure that they have access strictly to the data necessary to verify proper conduct of the Trial, guaranteeing the confidentiality of the same during the performance of the Trial. If the monitor is replaced, the Sponsor will inform the Centre of the monitor appointed in their place.

**1.5.-** The **SPONSOR** acknowledges that they are aware of each and every one of the obligations established by law for conducting observational trials in Spain and undertakes to comply with them, and accepts all the obligations and responsibilities deriving or arising from breach of same.

**1.6**.**-** The parties undertake to collaborate and keep each other informed concerning the Trial in order to ensure its success. To this end, the **SPONSOR** is obliged to present the **FOUNDATION** with a report on a six-monthly basis outlining the number of visits made and the number of patients enrolled, as well as any incidents that arose, upon conclusion of the trial.

**1.7.-** Access to clinical documentation is prohibited to anyone outside the Hospital and not authorized by the Center.

Access is only allowed to personnel hired by the **HOSPITAL**, both access to clinical documentation and to HCIS. It is totally forbidden to transfer the access codes to the HCIS by the **HOSPITAL** professionals.

TWO.- **AMENDMENT OR CANCELLATION OF THE TRIAL**

**2.1.-** The Trial may be amended or cancelled at the request of any of the parties or by mutual agreement under the following circumstances:

* impossibility of enrolling the minimum number of patients to enable the Trial to reach a final assessment in a reasonable time scale.
* force majeure.
* if an interim analysis of the existing data makes this advisable.
* by a decision of the EMA.

If the Trial is suspended, the sponsor will pay the **FOUNDATION** the amount due for the work performed, or, as appropriate, the **FOUNDATION** will reimburse the **SPONSOR** for any amount paid that has not been spent on work up to the time of suspension.

THREE.- **FINANCES**

**3.1**.- All details of the Trial finances must be set out in the attached trial budget (Schedule I).

**3.2**.- The estimated amount of the Trial (Schedule I) is \_\_\_\_\_ euro (€\_\_\_\_\_) per patient, plus the corresponding VAT, to be paid as provided in section 3.4 hereof. The trial budget will be split 78% for the RESEARCH TEAM and 22% for the FOUNDATION to cover indirect costs. That amount does not include any obligation or inducement for the **SERMAS** and/or the **INVESTIGATOR** to recommend, prescribe, buy, use or arrange the use of any of the **SPONSOR**’s products.The total contract amount (including contract-management expenses) will be € \_\_\_\_\_\_\_\_\_\_\_.

**3.3**.- The **SPONSOR** will pay the **FOUNDATION** all the amounts set out in the Financial Schedule by means of a bank transfer to the account that the **FOUNDATION** has at Banco Santander, C.C.C. 0049 1982 2128 1000 0070, (IBAN ES 31 0049 1982 2128 1000 0070/ SWIFT BSCHESMMXXX) within at most 60 days from presentation of the corresponding invoices issued correctly in the name of the **SPONSOR**.

Invoices for payments to patients will be issued and sent to:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tax ID \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Invoices for contract management expenses will be issued and set to the CRO:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tax ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**3.4**.- For the purpose of settling the full amount indicated in the preceding paragraph, the parties agree that the **SPONSOR** will pay the established amount as follows:

* a single non-reimbursable payment of €\_\_\_\_\_ for the FOUNDATION upon signature of this contract for managing/handling this contract.
* The remainder of the Amount, i.e. at most € \_\_\_\_\_\_\_\_\_\_\_\_, will be paid upon conclusion of the trial based on the number of evaluable subjects and the work actually performed.

**3.5**.- At the date of effective completion or suspension of the Trial, the **SPONSOR** and the **INVESTIGATOR** will inform the **FOUNDATION** of the number of subjects enrolled and the number of visits carried out to date, on the basis of which the **FOUNDATION** will issue the corresponding invoices, including those corresponding to the **INVESTIGATOR**. Once the **SPONSOR** has paid the invoiced amount, the **FOUNDATION** will immediately pay the corresponding amount to the **INVESTIGATOR**.

They must also report on any test, analysis, examination, appointment or hospital stay of an extraordinary nature that arose, whether or not they are reflected in the Financial Memorandum (Schedule I).

**3.6.-** The **INVESTIGATOR** is responsible for to propuse to the members of the research team and the support staff for the Trial; the team and staff must act independently and without any employment relationship with the **FOUNDATION** or the **SPONSOR** except with the foundation where any member of the team is a direct employee of the **FOUNDATION**.

FOUR.- **EXCLUSIVITY**

The **SPONSOR** declares that no agreements apart from this contract have been or will be entered into with the **INVESTIGATOR** and his/her co-workers that results in additional economic retribution or compensation in kind. This clause does not refer to the costs of meetings for organising the Trial or funds that the **SPONSOR** allocates in the future for disseminating the trial results in scientific meetings and publications.

FIVE.- **PROTECTION OF TRIAL SUBJECTS**

With regard to the data set out in this contract, each of the Parties is informed that the contact data of their representatives and employees will be processed by the other party for the purpose of performance, fulfilment and oversight of the research, the legal basis of the processing being the fulfilment of the contractual relationship; the data being kept for as long as the relationship subsists and thereafter until any liabilities deriving from it have expired. The Parties' data may be communicated to Public Administrations that are competent in the matter in order to comply with their respective legal obligations in accordance with the current legislation. The Parties may request access to personal data and may request that it be rectified or deleted, they may request portability or restrictions on processing, and may object to same, by giving notice to the address of the other Party at the beginning of this Contract.

Regarding the data of the subjects participating in the research, the **SPONSOR** is obliged to provide them, via the **INVESTIGATOR** with an informed consent form setting out the data that will be processed, the purpose of the processing, the third parties (public or private) that will have access to it, any international transfers, the retention periods, and the subjects' rights in the area of data protection.

In order to properly comply with the regulations, the **INVESTIGATOR** will carry out an appropriate process of dissociation of the personal data of the subjects participating in the study so that they cannot be identified or become identifiable by the **SPONSOR**, but the dissociation must be reversible for those situations in which it is necessary to re-identify any of the participating subjects. Only the monitors and/or designated representatives of the **SPONSOR**, auditors and competent authorities will have access to TRIAL subjects' personal data insofar as this is permitted by the informed consent and is for the purpose of performing their professional duties. In those cases, these purposes must be duly identified in the informed consent.

To the extent that the personal data of the Trial subjects is accessed and processed, the appropriate measures must be taken to protect such data and prevent access to it by unauthorised third parties. To this end, in conformity with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC and *Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente*, taking into account the level of technology, the application costs, and the nature, scope, context and purposes of the processing, along with the variable probability and severity of the risks to the rights and liberties of the trial subjects, the Parties will take such technical and organisational measures as are appropriate to ensure a security level which is commensurate with the risk, including, as appropriate, the following:

a) pseudonymisation and encryption of personal data;

b) permanent confidentiality, integrity, availability and resilience of the processing systems and services;

(c) the ability to restore availability and access to personal data quickly in the event of a physical or technical incident;

d) a regular process to verify, evaluate and assess the effectiveness of the technical and organisational measures to ensure processing is secure.

**RIGHT TO INFORMATION**. Each of the PARTIES is hereby informed that the professional contact details will be processed by the other party for the purpose of managing this contract, the legal grounds being the performance of this contract. The data will be stored while the contractual relationship persists and until any liabilities arising from it have lapsed. Furthermore, the PARTIES may not assign the data to third parties, except where there is a legal obligation to do so. Moreover, the PARTIES may, at any time, exercise their right of access, rectification, restriction, deletion, objection and portability with respect to their personal data, by writing to the PARTIES’ data protection officers:

Data Protection Officer (DPO) of FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO DE GETAFE:

Data Protection Officer (DPO) particulars:

Alaro Avant, S.L.

Avda. de Brasil 17, 7C, 28020, Madrid

dpo.fibgetafe@alaroavant.com

Data Protection Officer (DPO) of HOSPITAL UNIVERSITARIO DE GETAFE:

Comité DPD de la Consejería de Sanidad de la Comunidad de Madrid”, con dirección en Plaza Carlos Trías Bertrán nº 7 (Edif. Sollube) Madrid 28020

protecciondedatos.sanidad@madrid.org

SIX.- **DATA OWNERSHIP**

**6.1**.- The results, and the industrial property rights arising from the Trial that is the object of this contract will belong to the **SPONSOR**, without prejudice to the rights granted by law to the **INVESTIGATOR** and the **Foundation**. This circumstance will not prevent the use of the results in their professional activities.

**6.2**.- Upon request by the **SPONSOR**, the **FOUNDATION** or the **INVESTIGATOR** must provide the evidence required to apply for and obtain patents in any country or to protect the **SPONSOR**'s interests. The latter must compensate them for the time and expenses invested in these matters.

**6.3**.- The **SPONSOR** undertakes to publish the results of this Trial, whether positive or negative, in media such as articles, conferences, etc., also mentioning the CEIm that approved it. Before or after such publication, the **SPONSOR** may make the results of the Trial public through the **SPONSOR**'S on-line Register of Clinical Trials or by any other means. Any personal data concerning the **INVESTIGATOR** or any member of the team involved in the Trial will be covered by the **SPONSOR**'s data protection policy.

**6.4.-** For the proper publication of the results of the trial, the **INVESTIGATOR** is obliged to establish a procedure for anonymising the data of the subjects participating in the Trial so as to ensure that it is impossible to identify any of them.

**6.5.-** Both the **INVESTIGATOR** and his/her co-workers as well as **SERMAS** and the **FOUNDATION** undertake to respect the confidential nature of all the documentation derived from the drug owned by the **SPONSOR**, in addition to that resulting from the conduct of the Trial.

This confidentiality obligation will remain in force during the performance of the Trial that is the object of this Contract, and will subsist after its conclusion unless express written authorisation is given by the **SPONSOR**, describing the scope and content in detail.

**6.6.**- The PARTIES undertake to use all means at their disposal to guarantee the confidentiality of the information provided for performing the TRIAL and obtained during its performance, and of the personal data of the subjects enrolled for same, in order to comply with all the requirements of the current regulations. This confidentiality undertaking does not apply to information that:

- is in the public domain at the time it is disclosed by the **SPONSOR** to **SERMAS**, the **FOUNDATION** and/or the **INVESTIGATOR** or any person participating in the Trial.

- was already known by the **PRINCIPAL INVESTIGATOR**, by **SERMAS** and/or the **FOUNDATION** at the time of disclosure, provided that the source of the information is not directly or indirectly related to the **SPONSOR**.

- must be disclosed due to legal obligation.

- The processing of the personal data of subjects in the trial for purposes other than the investigation is strictly forbidden. The PI will establish the necessary security measures for the data, as well as its anonymisation in the publication of the results and is committed to maintaining the confidentiality of all information containing personal data of the participating subjects.

**6.7**.- The PI undertakes to maintain the security of the files generated relating to sensitive data of the participants in the trial in any type of format (paper, digital, electronic, etc.).

SEVEN.- **AUTHORISATION**

The SPONSOR and the PRINCIPAL INVESTIGATOR hereby confirm that the drug/medical device/diagnostic product evaluated in this observational trial will be used in an indication for which it is authorised in Spain, in the patient population for which it is authorised in Spain, under conditions of use authorised in Spain, and that its use in this trial conforms to standard clinical practice at the Hospital Universitario de Getafe.

EIGHT.- **ANTICORRUPTION CLAUSE**

The anti-corruption policy provides that no employee of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (**SPONSOR**) or of any third party acting for them or on their behalf may have any interest or commitment that clashes with their obligations under this Contract or prevents them from performing them in an appropriate and ethical manner, and all activities must be conducted in strict compliance with the standards of ethics and the applicable legislation. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (**SPONSOR**) considers integrity and transparency to be essential, and has a policy of zero tolerance for corrupt practices.

The employees of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (**SPONSOR**) or of any third party acting on their behalf may not enter into contact or authorise payments of any kind, either directly or indirectly, to any of the TRIAL participants in order to obtain an improper advantage or exert undue influence on any decision. The term "payments" refers to payments or promises of payment, in kind and/or in cash, and any other offer of goods or services.

The **FOUNDATION** must keep accurate records of all financial transactions arising from this Contract and will, when requested to do so in writing, make the relevant documentation available to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for verification of compliance with the commitments set out in this document.

NINE.- **JURISDICTION**

**9.1**.- The PARTIES expressly waive any other venue to which they might be entitled and agree that any dispute about the application or interpretation of the provisions of this Contract be submitted to the jurisdiction of the courts and tribunals of Madrid.

**9.2.-** Where a copy of this Contract is available in another language or tongue, the Spanish version will prevail.

In witness whereof, the PARTIES sign this document in [NUMBER OF COUNTERPARTS] counterparts, each an original in the place and on the date first written above.

XXXXXXXXXXX

**XXXXXXXXXXXXXXXXXXXXXX**

**Mr. XXXXXXXXXXXXXXXXX**

**PRINCIPAL INVESTIGATOR**

**Dr. XXXXXXXXXXXXXXXXXXXXXXXXX**

**FOUNDATION**

**Mr. Miguel Ángel Andrés Molinero**

\* En calidad de presidente del Patronato de la Fundación, conforme a los acuerdos de la Fundación elevados a escritura pública, con fecha 13 de junio de 2019.

**EL SERVICIO MADRILEÑO DE SALUD**

**Mr. Miguel Ángel Andrés Molinero\***

\* Resolución 385/2020, de 11 de junio, de la Viceconsejera de Asistencia Sanitaria, de Delegación de Competencias en materia de contratación y gestión económico-presupuestaria, published in BOCAM on 15 June 2020.

**SCHEDULE II**

**RESEARCH TEAM**